

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/717,688	11/22/00	KU	T 0-61930

SLIGHRUE, MION, ZINN, MACPHEAK & SEAS, PLL
2100 PENNSYLVANIA AVENUE, N.W.
WASHINGTON DC 20037-3213

HM22/0507

EXAMINER

WILLIS, M

ART UNIT	PAPER NUMBER
1619	5

DATE MAILED:

05/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/717,088	KO, THOMAS SAI YING
	Examiner	Art Unit
	Michael Willis	1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12 April 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

18) Interview Summary (PTO-413) Paper No(s) _____.

19) Notice of Informal Patent Application (PTO-152)

20) Other: _____

DETAILED ACTION

Claims 1-21 are pending. Claims 1-15 and 18-19 are drawn to a spray-on skin patch composition. Claims 16-17 are drawn to a spray patch skin delivery composition. Claims 20 and 21 are drawn to methods comprising applying to the skin a patch composition.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Oath/Declaration

2. The oath or declaration is defective because it does not identify the citizenship of each inventor. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 2, 4-6, 8, 9, 12 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 2 is confusing due to the phrase "water soluble compound comprises at least one physiologically active ingredient." Since a compound is a single chemical

structure, it is unclear how a compound can comprise an active ingredient. Changing “comprises” to “is” can obviate this rejection.

6. Claim 4 is rejected for being confusing due to the phrase “composition according to either claim 3 wherein”. This rejection can be obviated by the removal of the word “either”.

7. Claim 8 is rejected for being vague due to the phrases “phenol derivatives” and “azole derivatives and related compounds”. The specification fails to define derivatives and related compounds, thus the scope of the claim is unclear.

8. Claims 12 and 19 are rejected for being confusing due to the term “triclosane”. A chemical formula for triclosane could not be found. However, for purposes of examination, the term triclosane was considered to be the same as triclosan (5-chloro-2-(2,4-dichlorophenoxy)-phenol, CA registry number 3380-34-5). This rejection can be obviated by the substitution of the word “triclosan” for “triclosane”.

9. Any remaining claims are rejected for depending on an indefinite base claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 10, 11, 13, 15-17, and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Driggers et al (US Pat. 5,041,287). Driggers discloses a sprayable

composition using acetone as the solvent. The compositions form a coating on skin and are used to form a bandage or glove (see abstract). The compositions are comprised of polymers, an organic solvent, water, and a physiologically active substance (see col. 2, line 40 through col. 3, line 15). Preferred polymers include acrylic acid and methacrylic acid (see col. 3, line 28 through col. 4, line 24). The preferred solvent is acetone (see col. 4, lines 41-57). Plasticizers are included in the formulation (see col. 5, lines 10-28). Disclosed examples are comprised of acrylic acid, polyvinylidene difluoride, acetone, a plasticizer, and lidocaine or iodine, which serve as a pain relieving or antimicrobial agent, respectively.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tipton et al (US Pat. 5,632,727) in view of Modak et al (US pat. 5,708,023) and Driggers et al (US Pat. 5,041,287).

14. Tipton teaches a biodegradable film dressing and an apparatus for the spray delivery of the dressing (see col. 4, line 41 through col. 6, line 7). The biodegradable film can be used to protect and to promote healing of injured tissue and to deliver biologically active agents (see col. 2, lines 24-48). Solvents used include acetone (see

col. 6, lines 42-55). A water-soluble pore-forming agent can be included (see col. 7, lines 34-49). An antifungal agent for use in the composition includes tolnaftate (see col. 9, lines 28-67). Phthalic esters can be included as modifiers (see col. 10, lines 56-60). While the plasticizing property of phthalic esters is not taught, the property is inherent to the compound when incorporated into a film. The reference lacks use of acrylic acid as the film-forming polymer, chlorbutanol, triclosan, quaternary ammonium compounds such as cetrimide, and the specific percentages by weight of ingredients of the instant invention.

15. Modak teaches a method of inactivating irritants in a fluid contacting skin comprising applying a composition to the skin (see col. 2, lines 19-62). The active anti-irritant agents in the compositions of Modak include cetrimide, chlorbutanol, and triclosan (see col. 4, line 46 through col. 5, line 3). While Modak is silent regarding percentages by weight of the components, a difference in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

16. Driggers teaches the use of acrylic acid in a sprayable composition for forming a bandage on skin. The requirements for the spray-on bandage include non-toxic and non-irritating properties (see col. 1, lines 46-63). Driggers teaches that acrylic polymers are preferred in the composition (see col. 4, lines 1-19).

17. It would have been obvious to one of ordinary skill at the time the invention was made to have modified the compositions and methods of Tipton by the use of acrylic acid in order to benefit from its non-toxic properties as taught by Driggers and by the use of cetrimide, chlorbutanol, and triclosan in order to benefit from their anti-irritant properties as taught by Modak.

Conclusion

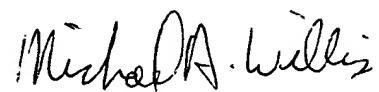
18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tipton et al (US Pat. 5,725,491) discloses a method of forming a biodegradable film dressing on tissue. Muchin et al (US Pat. 6,183,770 B1) discloses the use of triclosan in a carrier patch for the delivery of agents to the skin (see col. 9, line 60 through col. 10, line 6).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2742 for regular communications and (703) 308-2742 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Art Unit: 1619



Michael A. Willis, Ph.D.
Patent Examiner
May 4, 2001



Michael Hartley
Primary Examiner
Art Unit 1619